



07-30-07

TSW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Tami HAREL, et al.

Serial No.: 10/599,015 ✓

Filed: September 18, 2006

For: GASTROINTESTINAL METHODS AND
APPARATUS FOR USE IN TREATING
DISORDERS AND COTROLLING BLOOD
SUGAR

) Art Unit: (N/A)

) Examiner: (N/A)

) Washington, D.C.

) July 27, 2007

) Docket No.: MET095-
239431

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

[X] 1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

(Check one of the boxes A-D)

☐ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

[X] B. before the mailing date of a first office action on the merits.

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below).

(check one of the boxes "i" and "ii" below:)

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$240, is enclosed (check no. _____).

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. A check for the fee set forth in §1.17(i), presently believed to be \$130 is enclosed (check no. _____). Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

☐ 2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A and/or B and fill in blanks, if appropriate.)

☐ A. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial numbers and filing dates of prior applications]

Applicant identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 from the files of the prior application(s) or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

☐ 3. Documents ____ is (are) not in the English language. In accordance with 1.98(c), Applicant states:

☐ An English translation of each document ____ (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.

☐ A concise explanation of the relevance of document(s) _____ is found in the attached search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

☐ A concise explanation of the relevance of document(s) _____ is set forth as follows:
[Insert concise explanation of relevance]

☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.

☐ A concise explanation of document(s) _____ can be found on the attached sheet.

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

☐ 5. Other information being provided for the examiner's consideration follows:

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

Respectfully submitted,

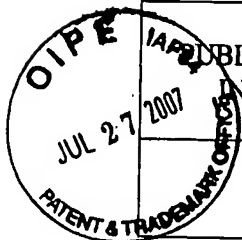
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July 27, 2007

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FORM PTO-1449 (Colb)	ATTY DOCKET NO. MET095-239431	SERIAL NUMBER 10/599,015
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANTS' INFORMATION STATEMENT	APPLICANT Tami HAREL, et al.	EXAMINER (N/A)
	FILING DATE September 18, 2006	GROUP ART UNIT (N/A)



U.S. PATENT DOCUMENTS

Examiner's Initials		DOCUMENT NO.	DATE	NAME	CLASS	SUB	FILING DATE
	AA	6,093,167	07-2000	Houben, et al.			
	AB	6,261,280	07-2001	Houben, et al.			
	AC	5,919,216	07-1999	Houben, et al.			
	AD	5,741,211	04-1998	Renirie, et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB	TRANS- LATION
	AE	WO 01/91854					
	AF	WO 00/53257					
	AG	WO 01/66183					

OTHER ART (Including Author, Bills, Pertinent Pages, Etc.)

	AH	Jaremko, et al., "Advances toward the implantable artificial pancreas for treatment of diabetes", Diabetes Care, 21(3), March 1998.
	AI	Lamb F.S. et al., "Cyclosporine augments reactivity of isolated blood vessels", Life Sciences, 40, pp. 2571-2578, 1987.
	AJ	Johansson B. et al., "Static and dynamic components in the vascular myogenic response to passive changes in length as revealed by electrical and mechanical recordings from the rat portal vein", Circulation Research, 36, pp. 76-83, 1975.
	AK	Zelcer E. et al., "Spontaneous electrical activity in pressurized small mesenteric arteries", Blood Vessels, 19, pp. 301-310, 1982.
	AL	Schobel H.P. et al., "Preeclampsia - a state of sympathetic overactivity", New England Journal of Medicine, 335, pp. 148-1485, 1996.
	AM	Rosenpire A.J. et al., "Pulsed DC Electric Fields Couple to Natural NAD(P)H Oscillations in HT-1080 Fibrosarcoma Cells", Journal of Cell Science, 114(Pt. 8), pp. 1515-1520, April 2001.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U.S. PATENT DOCUMENTS

Examiner's Initials		DOCUMENT NO.	DATE	NAME	CLASS	SUB	FILING DATE
	AA	5,101,814	04-1992	Palti			
	AB	5,190,041	03-1993	Palti			
	AC	5,368,028	11-1994	Palti			
	AD	5,314,463	05-1994	Camps, et al.			

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		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB	TRANS- LATION
	AE	WO 99/03533		PCT			
	AF	WO 98/10830		PCT			

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	AG	Gomis A. et al., "Oscillatory patterns of electrical activity in mouse pancreatic islets of Langerhans recorded in vivo", Pflugers Archiv European Journal of Physiology, Abstract Volume 432(3), pp. 510-515, 1996.
	AH	Soria B. et al., "Cytosolic calcium oscillations and insulin release in pancreatic islets of Langerhans", Diabetes Metab., 24(1), pp. 37-40, February 1998.
	AI	Magnus G. et al., "Model of Beta-cell mitochondrial calcium handling and electrical activity. II. Mitochondrial variables", American Journal of Physiology, 274(4 Pt 1): C1174-1184, April 1998.
	AJ	Yamada, "Effects of drugs on electromechanical activities of the stomach and duodenum of conscious dogs", Nippon Heikatsukin Gakkai Zasshi. 1983 Feb;19(1):25-35. (abstract only).
	AK	Nadal A. et al., "Homologous and heterologous asynchronicity between identified alpha-, beta-, and delta-cells within intact islets of Langerhans in the mouse", Journal of Physiology, 517(Pt. 1), pp. 85-93, May 1999.

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Examiner's Initials		DOCUMENT NO.	DATE	NAME	CLASS	SUB	FILING DATE
	AA	5,795,304	08-1998	Sun, et al.			
	AB	6,454,699	09-2002	Forsell			
	AC	4,485,805	12-1984	Foster, Jr.			
	AD	5,938,669	08-1999	Klaiber, et al.			
	AE	6,427,089	07-2002	Knowlton			

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	AF	WO 01/41671		PCT			

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	AG	M D Robertson, et al, "The influence of the colon on postprandial glucagons-like peptide 1 (7-36) amide concentration in man", Journal of Endocrinology (1999) 161, 25-31.
	AH	J Schirra, et al, "Mechanisms of the antidiabetic action of subcutaneous glucagons-like peptide-1 (7-36) amide in non-insulin dependent diabetes mellitus", Journal of Endocrinology (1998) 156, 177-186.
	AI	T Vilsboll and Associates, Research design and methods, Diabetes, Vol. 50, March 2001, pp. 610-613.
	AJ	Jeannie F. Todd, et al, "Subcutaneous glucagons-like peptide-1 improves postprandial glycaemic control over 3-week period in patients with early type 2 diabetes", Clinical Science (1998) 95, 325-329.
	AK	Daniel J. Drucker, "Development of glucagon-like peptide-1-based pharmaceuticals as therapeutic agents for the treatment of diabetes", Current Pharmaceutical Design, 2001, 7, 1399-1412.

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Examiner's Initials		DOCUMENT NO.	DATE	NAME	CLASS	SUB	FILING DATE
	AA	6,129,685	10-2000	Howard			
	AB	4,823,808	04-1989	Clegg, et al.			
	AC	5,868,141	02-1999	Ellias			
	AD	6,067,991	05-2000	Forsell			
	AE	5,601,604	02-1997	Vincent			
	AF	5,234,454	08-1993	Bangs			
	AG	4,133,315	01-1979	Berman, et al.			
	AH	4,416,267	11-1983	Garren, et al.			
	AI	4,592,339	06-1986	Kuzmak			
	AJ	5,991,649	11-1999	Garfield, et al.			

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	AK	WO 97/25098		PCT			
	AL	EP 1036545		EUROPE			

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AM	Shemerovskii KA, "Effect of feeding on the activity of duodenal smooth muscle in dogs", Biull Eksp Biol Med. 1978 Oct;86(10):394-7. (Abstract only).
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Examiner's Initials		DOCUMENT NO.	DATE	NAME	CLASS	SUB	FILING DATE
	AA	5,449,368	09-1995	Kuzmak			
	AB	5,226,429	07-1993	Kuzmak			
	AC	5,074,868	12-1991	Kuzmak			
	AD	5,690,691	11-1997	Chen, et al.			
	AE	5,423,872	06-1995	Cigaina			
	AF	5,188,104	02-1993	Wernicke, et al.			
	AG	5,263,480	11-1993	Wernicke, et al.			
	AH	6,104,955	08-2000	Bourgeois			
	AI	6,091,992	07-2000	Bourgeois			

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		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB	TRANS- LATION
	AJ	WO 02/082968		WIPO			
	AK	WO 01/83019		WIPO			

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Examiner's Initials		DOCUMENT NO.	DATE	NAME	CLASS	SUB	FILING DATE
	AA	5,836,994	11-1998	Bourgeois			
	AB	6,026,326	02-2000	Bardy			
	AC	3,411,507		Wingrove			
	AD	5,979,449	11-1999	Steer			
	AE	4,975,682	12-1990	Kerr, et al.			
	AF	5,861,014	01-1999	Familoni			
	AG	5,716,385	02-1998	Mittal, et al.			
	AH	5,995,872	11-1999	Bourgeois			
	AI	6,600,953	07-2003	Flesler, et al.			

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	AJ	EP 0057048	08-1982	EUROPE			
	AK	EP 0129483	12-1984	EUROPE			

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	AA	6,334,073	12-2001	Levine			
	AB	5,514,175	05-1996	Kim, et al.			
	AC	5,792,210	08-1998	Wamubu, et al.			
	AD	6,609,025	08-2003	Barrett, et al.			
	AE	6,735,477	05-2004	Levine			
	AF	2004/0147816	07-2004	Policker, et al.			
	AG	2004/0162595	08-2004	Foley			
	AH	6,658,297		Loeb			
	AI	6,092,528		Edwards			

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		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB	TRANS- LATION
	AJ	WO 05/037152					
	AK	WO 02/089655					

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	AA	5,690,691		Chen			
	AB	6,449,511		Mintchev			
	AC	6,243,607		Mintchev			
	AD	2002/0026141		Houben			
	AE	2003/0055464		Darvish			
	AF	5,704,368		Asano, et al.			
	AG	6,249,697		Asano, et al.			
	AH	5,795,304		Sun, et al.			
	AI	6,584,348		Glukhovsky			

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	AJ	WO 05/041749					
	AK	WO 04/069330					

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Examiner's Initials		DOCUMENT NO.	DATE	NAME	CLASS	SUB	FILING DATE
	AA	6,832,114		Whitehurst			
	AB	6,684,104		Gordon			
	AC	6,135,987		Houben			
	AD	5,368,028		Palti			
	AE	5,188,104		Wernicke			
	AF	6,381,495		Jenkins			
	AG	6,658,297		Loeb			
	AH	5,861,014		Familoni			
	AI	6,083,249		Familoni			

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		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB	TRANS- LATION
	AJ	WO 04/096337					
	AK	WO 03/020365					

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	AA	2004/0236316					
	AB	5,103,804					
	AC	6,869,431					
	AD	6,852,110					
	AE	6,939,349					
	AF	6,947,792					
	AG	6,745,079					
	AH	6,405,732		Edwards			
	AI	6,612,983		Marchal			
	AJ	6,658,297		Loeb			
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		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB	TRANS- LATION
	AL	EP 1 447 052					

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	AA	2005/0143784					
	AB	6,754,536					
	AC	2003/0220678					
	AD	2005/020965					
	AE	6,876,885					
	AF	2004/0088023					
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	AI	2005/0065505					

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	AJ	WO 05/087310					
	AK	WO 04/066903					

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	AA	2005/0107829					
	AB	5,247,938					
	AC	5,105,812					
	AD	6,826,428					
	AE	2005/0075654					
	AF	5,551,425					
	AG	6,132,372					
	AH	2004/0193184					
	AI	6,535,764					

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	AA	4,280,503		Ackerman			
	AB	3,516,412					
	AC	4,378,023		Trabucco			
	AD	6,216,045		Black, et al.			
	AE	6,363,937					
	AF	6,606,523					
	AG	2004/0158138					
	AH	2005/0203500					
	AI	2005/0183732					

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		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB	TRANS- LATION
	AJ	WO 05/007232					
	AK	EP 144705					
	AL	WO 05/037152					

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U.S. PATENT DOCUMENTS

Examiner's Initials		DOCUMENT NO.	DATE	NAME	CLASS	SUB	FILING DATE
	AA	2004/0162469		Imran			
	AB	2004/008023		Imran, et al.			
	AC	2005/0021101		Chen, et al.			
	AD	6,754,536		Swoyer, et al.			
	AE	6,600,953		Flesler, et al.			
	AF	2004/0059393		Policker, et al.			
	AG	6,415,178		Ben-Haim, et al.			
	AH	6,571,127		Ben-Haim, et al.			
	AI	6,895,279		Loeb, et al.			

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		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB	TRANS- LATION
	AJ	WO 05/023081					
	AK	WO 04/112563					
	AL	WO 02/089655					

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FORM PTO-1449 (Colb)	ATTY DOCKET NO. MET095-239431	SERIAL NUMBER 10/599,015
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANTS' INFORMATION STATEMENT	APPLICANT Tami HAREL, et al.	EXAMINER (N/A)
	FILING DATE September 18, 2006	GROUP ART UNIT (N/A)

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Examiner's Initials		DOCUMENT NO.	DATE	NAME	CLASS	SUB	FILING DATE
	AA	4,000,745		Goldberg, et al.			
	AB	4,357,946		Dutcher, et al.			
	AC	4,313,448		Stokes			
	AD	4,177,818		De Pedro			
	AE	2005/0183732		Edwards			
	AF	2005/0107829		Edwards, et al.			
	AG	2003/0220678		Tronnes, et al.			
	AH	2004/0088023		Imran, et al.			
	AI	2005/0065505		Ryan			

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		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB	TRANS- LATION
	AJ	WO 06/118790					
	AK	WO 05/007237					
	AL	WO 05/016181					

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	AA	5,247,938		Silverstein, et al.			
	AB	6,754,536		Swoyer, et al.			
	AC	6,876,885		Swoyer, et al.			
	AD	6,745,079		King			
	AE	6,852,110		Roy, et al.			
	AF	3,737,579		Bolduc			
	AG	4,010,758		Rockland, et al.			
	AH	4,235,246		Weiss			
	AI	4,452,254		Goldberg, et al.			

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	AJ	WO 04/096337					
	AK	JP 2003319945					
	AL	WO 03/020365					

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	AA	2002/0103424		Swoyer, et al.			
	AB	2005/0055038		Kelleher, et al.			
	AC	6,363,937		Hovda, et al.			
	AD	2004/0158138		Kilcoyne, et al.			
	AE	2005/0203500		Saadat			
	AF	2005/0075654		Kelleher			
	AG	2004/0193184		Laufer, et al.			
	AH	5,423,872		Cigaina			
	AI	5,837,006		Ocel, et al.			

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	AJ	JP 2003/319945					
	AK	WO 04/043280					

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	AA	6,826,428		Chen, et al.			
	AB	2005/0192615		Torre, et al.			
	AC	2005/0143784		Imran			
	AD	6,535,764		Imran, et al.			
	AE	6,606,523		Jenkins			
	AF	6,041,258		Cigaina, et al.			
	AG	2003/0195600		Tronnes, et al.			
	AH	2005/0209653		Herbert, et al.			
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	AJ	WO 94/01172	01-1994	WIPO			
	AK	WO 06/035446		WIPO			

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	AA	6,591,137	07-2003	Fischell, et al.			
	AB	6,735,477	05-2004	Levine			
	AC	2006/0247718	11-2006	Starkebaum			
	AD	5,101,814	04-1992	Palti			
	AE	6,572,542	06-2003	Houben, et al.			
	AF	6,652,444	11-2003	Ross			
	AG	2003/0208242	11-2003	Harel, et al.			
	AH	2004/0249421	12-2004	Harel, et al.			
	AI	2003/0144708		Starkebaum			
	AJ	2006/0142803		Mintchev			
	AK	7,054,690		Imran			

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	AL	WO 02/053093		WIPO			

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AM	U.S. Patent Application Number 10/237,263.
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	AA	2003/0208212		Cigaina			
	AB	2006/0173238		Starkebaum			
	AC	2004/0167583		Knudson, et al.			
	AD	2005/0222638		Foley, et al.			
	AE	2003/0066536		Forsell			
	AF	2001/0011543		Forsell			
	AG	7,076,306		Marchal, et al.			
	AH	2005/0090873		Imran			
	AI	7,076,305		Imran, et al.			
	AJ	6,853,862		Marchal, et al.			
	AK	6,115,635		Bourgeois			

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Examiner's Initials		DOCUMENT NO.	DATE	NAME	CLASS	SUB	FILING DATE
	AA	5,540,730		Terry, et al.			
	AB	7,043,295		Starkebaum			
	AC	2004/0044376		Flesler, et al.			
	AD	2004/0107004		Levine, et al.			
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	AI						
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